



Collette N.V.

Designed for Success

Results

- S88 standardization
- Integrated 21 CFR Part 11 support
- Centralized storage of both batch and process data

"The growing demands of our customers to adhere to standards like S88 and 21 CFR Part 11 was the most important reason to choose a standard package that could keep pace with this kind of technology."

Heinrich Meintrup
Managing Director
Collette NV

S88 Standard Makes Machine Control More Flexible and Easier to Maintain - with Automation from Novotek and GE Fanuc

As one of the world's leading machine manufacturers, Collette NV offers a wide range of equipment for mixing, granulating and drying of pharmaceutical or fine-chemical products. A new series of processing equipment has been developed, combining mixing and granulator functions with several drying options including vacuum, gas-assisted and microwave drying into a single machine, with standard batch management and control provided by **Novotek** and GE Fanuc's iBatch™*.

The increasing complexity of the PLC Control Logic and the increasing demand for S88 and 21 CFR Part 11 compliant systems made Collette search for a standard solution. A PC-based control system according to S88.01 and 21 CFR Part 11 standards helped them to simplify the control, yet leverage the ultimate flexibility to their end users.

Benefit from Standards

S88 applies for standard terminology and a logical subdivision of both equipment and recipes. As part of the concept, the control in the PLC is broken down into logical phases controlling independent



* Part of Proficy Intelligent Production Solutions from GE Fanuc.

equipment modules. A standard Phase Logic Interface takes care of a universal communication protocol and handshake mechanism from PC to PLC.

Ergonomic User Interface

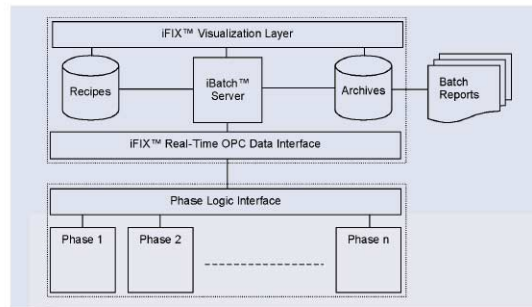
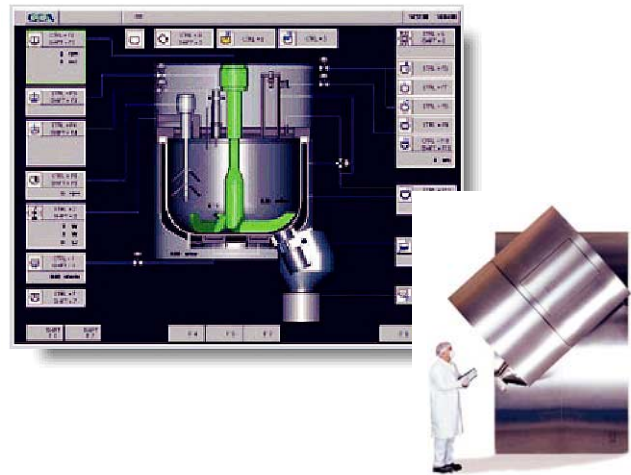
Since Collette wanted to provide end users with uncompromising functionality, the front-end user interface was implemented in the tightly integrated iFIX™* SCADA package from GE Fanuc. This resulted in a very intuitive and easy-to-use execution environment, yet leaving the iBatch Engine in charge of the execution, control and information recording of batches. The user interface enables operators to build and validate new recipes in just a few minutes, run batches in automatic mode and take over manual control of the individual equipment modules to fine-tune running operations.

Improved Maintenance and Backup

The PC based control concept simplified the PLC logic dramatically. Interfacing is now standardized and information recording centralized. Both batch related and detailed process data is stored into one central database, where it can be used for reporting and/or exporting. This also facilitates the data-validation requirements.

21 CFR Part 11 Requirements

Since the FDA approved the usage of Electronic Signatures and Electronic Records, there has been an increasing demand of 21 CFR Part 11 compliant systems. Electronic validation is an important feature of the standard packages iFIX and iBatch so that most requirements could easily be integrated. The open system architecture still left room for customization of specific functional requirements.



GE Fanuc Automation Information Centers

USA and the Americas:
1- 800-GE FANUC
or (434) 978-5100

Europe, Middle East and Africa:
(352) 727979-1

Asia Pacific:
86-21-3222-4555

Additional Resources

For more information, please visit the GE Fanuc web site at:

www.gefanuc.com

